REMARKS

Applicants request reconsideration of this application in view of the foregoing amendments and the following remarks.

Claims 1-51 are pending in this application, with claims 1, 9, 17, 26, 35 and 42 being independent. Claims 1, 8, 9, 16, 17, 26, 35 and 42 have been amended to correct certain typographical errors and to more specifically recite and distinctly claim Applicants' invention.

Claims 1-51 have been rejected under 35 U.S.C. 112, first paragraph, as not being enabled. The Office Action notes, at page 2, that the specification "while enabling for treating allergic or inflammatory conditions, does not reasonably provide enablement for preventing said conditions using a single drug as claimed." Without agreeing with this comment, and solely in an effort to advance prosecution in this application, Applicants have amended each of the independent claims to remove the "preventing" language in such claims. Accordingly, Applicants submit that the enablement rejection is now moot and should be withdrawn.

Claims 9-16 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of use of the term "substantially" in those claims. The Office Action posits, at page 6, that "[t]he term 'substantially the same' is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." Applicants respectfully traverse this rejection.

As noted in MPEP ¶ 2173.05(b)

> "When a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention."

Applicants' discussion of the pharmacokinetic results for Study Nos. 1 and 2 provide guidance on the meaning of the term "substantially" in claim 9, as well as the meaning of that term in claims 26 and 42. (*See, in particular,* Table II at page 12 with respect to Study No. 1 and Table IV at page 20 with respect to Study No. 2.)

Moreover, the term "substantially" in independent claims 9, 26 and 42 is used by Applicants to include that range of values (i.e., 80%-125% of the recited value) that is considered to be bioequivalent for a systematically absorbed formulation, as understood by a person having ordinary skill in the art. (*See* 21 C.F.R. § 320.1 for a definition of "bioequivalence." *See also, e.g.,* Food and Drug Administration, Guidance for Industry – Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations (March 2003) at p. 20 for a discussion of the 80%-125% bioequivalent range of values.) Each of independent claims 9, 26 and 42 contemplates treating a human for certain conditions comprising administering an effective amount of desloratadine "while obtaining substantially the same bioavailability of desloratadine under fed or fasted conditions." Bioequivalence, as a concept, contemplates the availability of an active ingredient at a site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. (*See* the definition of "bioequivalence" at 21 C.F.R. § 320.1.) Consequently, it is appropriate for the term "substantially" to contemplate an 80%-125% range in each of independent claims 9, 26 and 42 for the bioavailability to be obtained for desloratadine under fed or fasted conditions.

Therefore, Applicants believe that the term "substantially" is a specific and definite limitation that clearly delineates the metes and bounds of Applicants' invention, as recited in claims 9, 26 and 42. Accordingly, use of the term "substantially" does not render the rejected claims indefinite. Applicants therefore request that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

Finally, claims 1-51 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,595,997 to Aberg, et al., or alternatively in view of a Claritin® Instruction Sheet included with the Office Action. Applicants respectfully submit that this rejection should be withdrawn because the Office Action applies the incorrect standard for inherent anticipation. Moreover, Applicants traverse this rejection because the cited documents neither teach nor suggest Applicants' claimed invention individually or in combination.

As the Federal Circuit confirmed in Continental Can Co. v. Monsanto Co., 948 F.2d 1264 (Fed. Cir. 1991), "[i]nherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of

circumstances is not the test." The proper test for inherent anticipation is whether the claimed invention "necessarily results from" the disclosure in the allegedly inherently anticipating reference. (*See, e.g.,* Rapoport v. Dement, 254 F.3d 1053, 1062-63 (Fed. Cir. 2001), and Schering Corp. v. Geneva Pharmaceutials, Inc., 339 F.3d 1373, 1381 (Fed. Cir. 2003).) Therefore, the Office Action's suggestion that one might "envision," "readily envisage" or "easily envision" Applicants' claimed invention, even if true, which Applicants do not concede, would not be enough. *See, for example,* the Office Action at: page 8, lines 8-12; page 8, line 17 to page 9, line 1; and page 9, lines 1-2. *See also* MPEP ¶ 2112, part IV.

In the Rapoport case, the Federal Circuit found that, in challenging the validity of a claim based on inherent anticipation, Rapoport failed to meet the applicable evidentiary standard, since it failed to offer positive evidence that the prior art necessarily results in the method of the treatment contemplated in the patent. Indeed, the Federal Circuit held that Rapoport failed to foreclose the possibility that other factors were needed to combine with the prior art in order to reach the claimed invention. *See also* Toro Co. v. Deere & Co., 355 F.3d 1313, 1314 (Fed. Cir. 2004) (no inherent anticipation if outside factors are capable of intervening between the prior art and the challenged invention).

Applicants submit that the Office Action does not offer any positive evidence that Applicants' claimed invention "necessarily results from" the disclosure in the Aberg et al. patent. The Aberg et al. patent describes a method of treating allergic rhinitis in a human while avoiding the concomitant liability of adverse side-effects associated with the administration of non-sedating antihistamines, which involves administering to a human a therapeutically effective amount of descarboethoxyloratadine (i.e., DCL or desloratadine) or a pharmaceutically acceptable salt thereof. The adverse side-effects include, but are not limited to, cardiac arrhythmias, cardiac conduction disturbances, appetite stimulation, weight gain, sedation, gastrointestinal distress, headache, dry mouth, constipation, and diarrhea. (*See* col. 4, lines 58-64 and col. 8, lines 3-9 of Aberg et al.)

In contrast, claims 1, 17 and 35 each recites a method of treating a specified condition in a human while avoiding a food effect. The claimed method involves orally administering to the human in need thereof under fed or fasted conditions an amount of

desloratadine effective for such treating while avoiding a food effect on the bioavailability of desloratadine. Claims 9, 17 and 42 each recites a method of treating a specified condition in a human in need thereof that involves orally administering to the human an amount of desloratadine effective for such treating, while obtaining substantially the same bioavailability of desloratadine under fed or fasted conditions. In claims 1 and 9, the condition being treated is allergic and inflammatory conditions of the skin or airway passages. In claims 17 and 26, the condition being treated is seasonal or perennial allergic rhinitis. In claims 35 and 42, the condition being treated is atopic dermatitis or urticaria.

In other words, in the claimed invention, Applicants seek to administer an amount of desloratadine: (1) so as to avoid a food effect on the bioavailability of desloratadine (as recited in claims 1, 17 and 35); or (2) such that its bioavailability under fed or fasted conditions is substantially the same (as recited in claims 9, 26 and 42).

Applicants' claimed invention does not "necessarily result" from the disclosure in the Aberg et al patent. The Aberg et al. patent neither teaches nor suggests how food intake might affect the bioavailability of desloratadine when administered to a human.

The OTC instruction sheet for Claritin® also does not teach or suggest Applicants' claimed invention individually or in combination with the Aberg et al. patent. The instruction sheet merely notes that loratadine, which is the active ingredient in Claritin®, is to be administered on an empty stomach but makes no mention whatsoever of desloratadine.

Consequently, Applicants submit that the rejection under 35 U.S.C. 102(b) should be withdrawn.

Applicants submit that each of the presently outstanding rejections has been addressed and that the currently pending claims are in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

By Natalie M. Derzko

Paul J. Berman
Registration No.: 36,744
Natalie M. Derzko
Registration No.: 48,102
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401
(202) 662-6000